NATIONAL INSTITUTES OF HEALTH

A PLAN FOR MANAGING THE COSTS OF BIOMEDICAL RESEARCH

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
National Institutes of Health

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INTRODUCTION

Over the past 40 years there has been national consensus that federally funded biomedical research is important to improving human health. This policy has led to an unprecedented series of remarkable discoveries and to the ascendancy of the United States in the field of biomedicine. The progression from basic research, to targeted research, to the adoption of new health care technologies has played a vital role in improving and prolonging human health. In this process it has also fostered economic competitiveness and increased productivity, thus contributing to overall growth of the national economy.

Current fiscal constraints at the national level have compelled an evaluation of federal expenditures, including support of biomedical research and training. The House of Representatives and Senate Appropriation Reports (101-591 and 101-516, respectively) reaffirm the historical Congressional commitment to a healthy biomedical research enterprise, as reflected by the provision of substantial resources for FY 1991. At the same time, however, the reports express concern over the lack of a clear plan for cost management and control to provide stability and predictability in the aggregate funding level for research during a period in which unprecedented opportunities for scientific progress appear to outstrip the federal resources that realistically can be made available (Appendix A).

The House of Representatives and Senate reports outline several goals that Congress and NIH have in common:

- supporting only highly meritorious biomedical research to sustain progress in combating disease and improving human health;

- making optimal use of limited federal resources through cost management and containment to support, in a balanced manner, the full range of funding mechanisms such as investigator-initiated projects, research and resource centers, and research training; and

- providing stability and predictability in the aggregate funding level for research in order to maintain the momentum in the advancement of biomedical knowledge generated by past and current investments in biomedical research.

Using these goals as a framework, NIH has developed a financial management plan to ensure the future vitality of the biomedical research enterprise within the available appropriated funds.

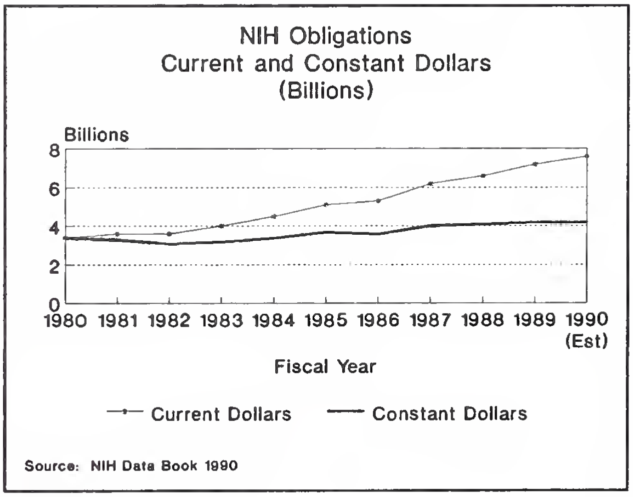
BACKGROUND

Stability and predictability in the aggregate funding level for biomedical research are essential to maintaining the momentum in knowledge advancement that results from our investment in biomedicine. They are also essential to reassure scientists that their years of training will result in reasonable competitive opportunities to pursue and maintain a research career. Within the context of the NIH financial management plan, it must be emphasized that the paired goals of stability and predictability will be pursued with the understanding that the NIH will continue to place its highest priority on research that is both highly meritorious and strongly relevant to improving human health.

In developing this financial management plan, it is important to reiterate the fact that NIH has traditionally managed only those costs within its direct control. For example, NIH has had little independent control over the indirect costs of research grants and hospital-based clinical research costs. Furthermore, inflation has a strong negative influence on biomedical research in that it erodes NIH's ability to pursue scientific opportunities while exaggerating the real growth of the scientific enterprise. In order to correct for inflationary changes, NIH uses the Biomedical Research and Development Price Index (BRDPI), a measure that provides a more accurate and realistic assessment of inflationary growth in biomedical research costs. The BRDPI, a price index developed by the Department of Commerce, measures the effects of changes in costs associated with personnel, equipment, and supplies specifically used in biomedical research. While the BRDPI is generally one to two percent higher, it is a more accurate index of inflation in the biomedical research marketplace than the more general, well-known price indices such as the Consumer Price Index or the price deflator for the Gross National Product (GNP).

Prior to addressing specific elements of the financial management plan, it may be useful to review some of the data that constitute the experience of NIH during the 1980s. The most recent data are used where available. In most instances these include FY 1989 while in others it has been possible to provide reliable estimates for FY 1990.

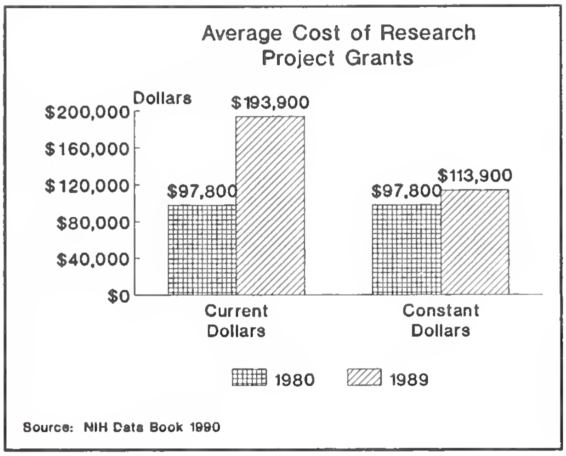
o **NIH Obligations** - NIH obligations have grown in current or non-deflated dollars from $3.4 billion in FY 1980 to an estimated $7.6 billion in FY 1990, an increase of 124%. When corrected for inflation using the BRDPI, NIH obligations increased 24% from $3.4 billion to $4.2 billion. This represents an annualized real change of 2.1 %. (Figure 1)



Source: NIH Data Book 1990

Figure 1

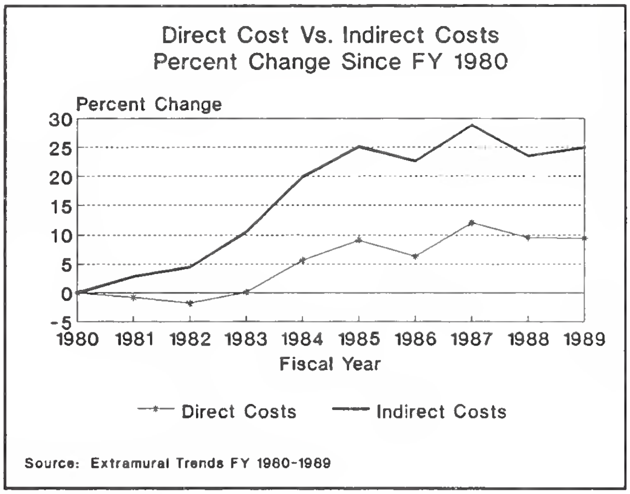
- **Average Cost of Research Project Grants** - Following downward negotiations, the average cost of a research project grant (RPG), in current dollars, has risen from $97,800 in FY 1980 to $193,900 in FY 1989, a 98% increase. However, when inflation is factored out using the BRDPI, the average cost in constant dollars increased by 16% to $113,900 in FY 1989. This represents an annualized real change in the average cost of RPGs of 1.7%. (Figure 2)



Source: NIH Data Book 1990

Figure 2

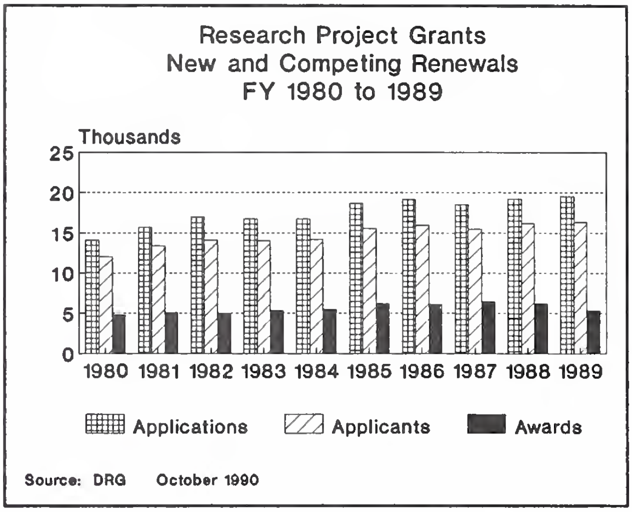
- **Direct v. Indirect Costs of Traditional Research Grants (R01)** - The increase in indirect costs outpaced that in direct costs by a factor of two and one-half between FY 1980 and FY 1989. There was a 24.9% change in constant dollar indirect costs (i.e., from $24,974 in FY 1980 to $31,190 in FY 1989) compared to a 9.4% change in constant dollar direct costs (i.e., from $59,252 in FY 1980 to $64,821 in FY 1989). Thus the annualized real change in indirect costs was 2.5% while the annualized real change in direct costs was 1.0%. However, between FY 1984 and FY 1989, the increase in indirect costs as compared to that in direct costs was less dramatic. (Figure 3)



Source: Extramural Trends FY 1980-1989

Figure 3

- **Number of Applications and Applicants** - The total number of new applications and competing renewal applications grew by 5,393, from 14,142 in FY 1980 to 19,535 in FY 1989, a 38% increase. During this same period the total number of applicants submitting new and competing renewal applications increased by 4,307, from 12,090 in FY 1980 to 16,397 in FY 1989, a 36% growth. (Figure 4)

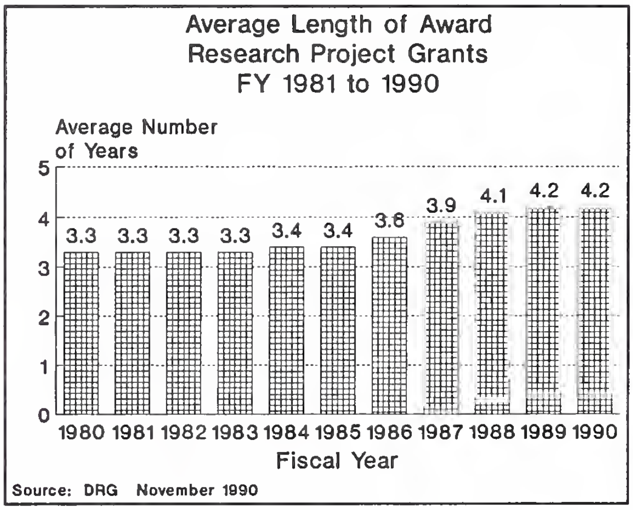


Source: DRG October 1990

Figure 4

- **Number of Awards** - At the same time that the number of applications and applicants increased 38% and 36%, respectively, new and competing renewal grant awards grew by 598, from 4,785 in FY 1980 to 5,383 in FY 1989, representing a 12% increase. (Figure 4)

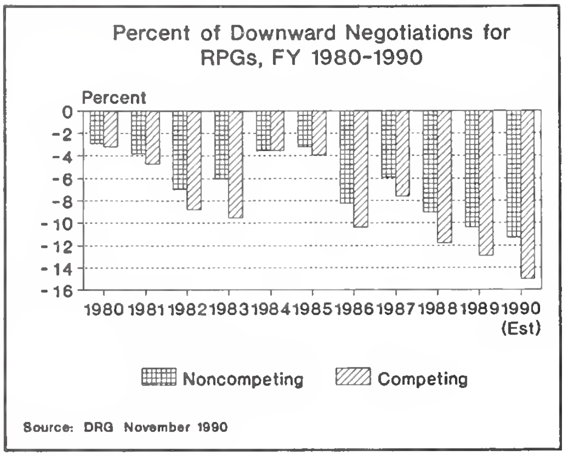
- **Average Length of Research Grants** - The average length of research grants increased from 3.3 years in FY 1980 to 4.2 years in FY 1990. (Figure 5)



Source: DRG November 1990

Figure 5

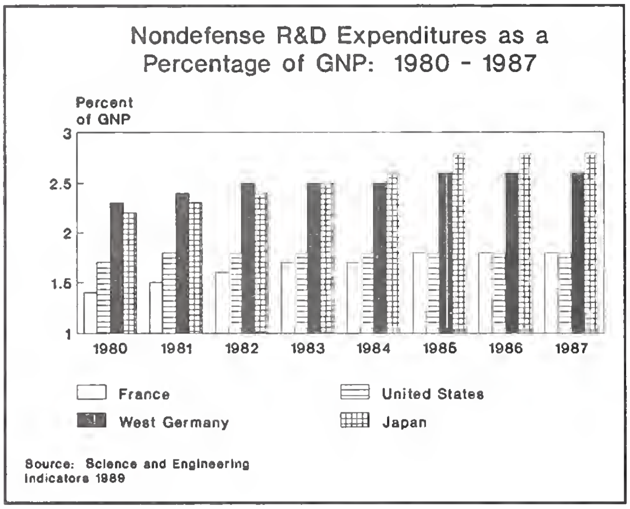
- **Downward Negotiations for Competing and Non-competing Research Project Grants** - The practice of funding research project grants (RPGs) at a level below the initial review group recommended level is referred to as "downward negotiation". For competing RPGs, the size of these reductions has grown from an average of 3.2% in FY 1980 to an estimated 15.0% in FY 1990. For non-competing RPGs the average reduction of 2.9% in FY 1980 increased to an estimated 11.3% in FY 1990. (Figure 6)



Source: DRG November 1990

Figure 6

- **Non-defense R&D Expenditures as a Percentage of GNP** - Japan and West Germany have dedicated a larger percentage of GNP than the U.S. to non-defense R&D. Since 1981, the rate of civilian R&D investment, as a percentage of GNP, for Japan, West Germany, and France has also been rising faster than that of the U.S. Between 1980 and 1987 (the last year for which comparable data are available), Japan's non-defense R&D increased by 0.6%, France's by 0.4%, and West Germany's by 0.3%, while the United States' non-defense R&D increased by 0.1%. (Figure 7)



Source: Science and Engineering Indicators 1989

Figure 7

Substantial Congressional appropriations for NIH over the past decade have supported significant growth of the national biomedical research enterprise. Expansion in support for NIH programs, growth in the number of highly trained, skilled investigators and increases in the number of research awards have resulted in notable scientific accomplishments and many new lines of investigation. The increased numbers of research grant applications and awards testify to a flourishing national biomedical research endeavor. For example, the President's FY 1992 Budget proposes increasing support for research project grants by 8.8%, enough to provide 3% real growth (after adjusting for inflation using the 1992 Biomedical Research and Development Price Index of 5.8%). This real growth ensures that the portion of the nation's GNP devoted to HHS-supported biomedical and behavioral research will continue to grow. Totaling .12% of the GNP in

1970, HHS-funded research grew to .14% in 1980, and will be .16% in 1992 at the level requested in the President's Budget.

However, the changing nature of biomedical research, exploiting the astounding advances in molecular biology, immunology and neuroscience (to name only three), increasingly involves the use of very costly facilities, equipment, and techniques. As the tools of research have shifted from petri dishes and test tubes to DNA sequencers, MRI instrumentation and supercomputers, so too have its costs increased. The cost of science increases as research problems become more complex and the infrastructure needed to support inquiry grows more sophisticated and expensive. This increase in the scientific, technological as well as regulatory complexity of biomedical research makes it clear that the annualized growth in the average cost of a research project grant of only 1.7% is, in truth, surprisingly low. Although the BRDPI may be a reasonable measure for gauging the effects of inflation on the costs of personnel and even supplies, as research becomes more complex and resource intensive, the BRDPI may be misleading relative to the impact of technological advances on project costs.

The biomedical research community is entering the 1990s with unprecedented opportunities for new discoveries that will improve human health. In the coming decade, we must confront simultaneously the economic realities of genuine and substantial increases in the costs of conducting biomedical research and the prospect of pronounced constraints on growth in funding.

In this spirit, NIH has developed the financial management plan called for by the House and Senate Appropriations Committees. The plan provides for cost containment of the existing enterprise but recognizes the reality that there are indeed "unique problems or initiatives which will need to be considered outside of this funding framework", as stated in the House Appropriations Report. It also recognizes the need for continuing evolution of the plan in consultation with Congress and the biomedical research community. Evaluation of the impact of its provisions and improved communications of cost information must accompany this evolution. NIH must strike a balance among the precision and predictability required for cost containment, the stability called for by the research community, and the preservation of flexibility needed to capitalize on unique scientific opportunities.

FINANCIAL MANAGEMENT PLAN

In preparing this financial management plan, NIH has built upon the proposals suggested by both the House and the Senate in their respective appropriations reports. It is based on the following principles:

- To ensure that NIH supports the highest quality biomedical research, peer review will continue to have as its primary focus the evaluation of the scientific merit of research that is proposed for funding.

- Investigator-initiated research project grants will continue to be accorded highest priority among all types of extramural awards.

- In order to carry out its mission, each NIH Institute and Center must strive for a balanced research portfolio manifesting an individually appropriate mix of research project grants, center grants, training grants, and other mechanisms.
- NIH policies and procedures must be sufficiently flexible to allow biomedical science to be responsive to public health emergencies and emerging scientific opportunities.
- Cost management goals can and should be pursued through a combination of peer review actions and administrative controls.

In keeping with the intent of Congress, this plan is designed to meet the following goals:

(a) Fix the average length of research project grants at four years for the foreseeable future. This length preserves the important gains of the 1980s with respect to funding continuity for individual investigators and still ensures that a sufficient number of competing awards are made each year. If, on the basis of further analysis and experience, the NIH decides to increase the average duration above four years, the NIH will update this financial management plan to indicate how that is to be achieved within overall budget constraints.

(b) Implement cost-management measures so that the average cost of competing research project grants, on an Institute-by-Institute basis, increases in consonance with the Biomedical Research and Development Price Index (BRDPI).

(c) Establish the indirect cost rate negotiated for the initial (competing) year as the rate for all years of the recommended period of support.

(d) Abolish use of the concept of "approving" grant applications and adopt the success rate (i.e., the ratio of applications funded to applications reviewed) to quantify the relationship between resources and requests. The success rate is widely used in other federal agencies.

(e) Fund research training at the numbers recommended by the National Academy of Sciences to the extent possible without jeopardizing NIH's ability to provide stipend increases for research trainees.

(f) Increase funding for "Other Mechanisms" commensurate with inflationary costs to the extent possible within overall budget constraints.

RESEARCH PROJECT GRANTS

A. Length of Grant Awards

In the late 1970s and early 1980s, in an attempt to ensure more stability in research grant support and to reduce the time investigators were expending in preparing grant applications, NIH began to award grants for longer periods of time. Over the last decade, the average length of research project grants, consisting primarily of regular

R01 grants, program project grants and FIRST awards, has shifted upward from three years, such that the average length in FY 1990 was approximately 4.3 years. In response to Congressional concern over this matter, NIH agrees to establish an average award length of approximately four years, starting with competing grant awards made in FY 1991. This can be achieved by awarding an appropriate mix of three-year and five-year grants, by emphasizing four-year grants or by a combination of both approaches. NIH Institutes and Centers will still be able to make longer-term awards as long as their portfolios also contain a sufficient number of shorter-term grants so that the necessary balance is achieved.

Although holding the average award length to approximately four years will ensure cost containment in the short run, some negative implications may emerge as significant in the long term. For example, to the extent that investigators spend more time than necessary preparing grant applications, this will require more resources to review and evaluate them. Furthermore, competing continuation grant applications have traditionally shown significant budgetary increases over the previous non-competing grant, i.e., well above the BRDPI.

NIH therefore will need to evaluate carefully the full impact of setting the average grant duration at four years and, if the analysis indicates that it should be increased, develop a strategy to manage the introduction of this modification to the financial management plan.

B. Costs and Numbers of Grant Awards

On the basis of its peer review process, NIH selects from among only the most scientifically meritorious proposals relevant to the research missions of its Institutes and Centers. The initial review groups (IRGs) provide an assessment of the scientific merit of a proposed project and recommendations for the appropriate level of support and duration of award. The second level of review by the National Advisory Councils/Boards provides recommendations regarding adequacy of the IRG assessment, overall scientific priorities, program balance, and funding policies.

It is important that the IRGs continue to carry out their mandated role to provide Councils/Boards and Institute/Center staff with information on the relative scientific merit of a proposed project as well as the appropriate support level and duration. In their role as scientific evaluators, the IRGs regularly impose significant reductions on proposed direct costs. Notwithstanding this practice, it would be inappropriate to involve them in judgments regarding the indirect costs of applicant institutions since those are issues well beyond the assessment of scientific and technical merit and well beyond peer reviewers' expertise.

Some recent discussions have centered on the comparison of budget reductions recommended by IRGs and those made by the awarding Institutes and Centers. Appendix B displays the percentage reductions that have been made on research project grants awarded during the period from FY 1980 through FY 1990. Although there is an overall inverse correlation between the reductions recommended by the IRGs and those made by the Institutes/Centers, it is not clear that there is a causal relationship. A close examination of the data shows that the better the priority scores, the smaller the reductions recommended by the IRGs in any given year. For example, in FY 1980, although the average IRG reduction was 21.9%, the reductions for the first and second quartile of awards were actually 14.4% and 20.5% respectively. Even as recently as FY 1990, there was still a two-fold difference in IRG recommended reductions between the first and fourth quartile of awards (8.2% v. 16.2%). Furthermore, as the quality of applications has increased over the past decade and funding is increasingly limited to those applications with the most favorable scores, it is highly unlikely that, even with the most rigorous budget scrutiny today, IRGs will be able realistically to make the same level of reductions as they did in the early 1980s. Nonetheless, the negative correlation evident in the data in Appendix B is of sufficient concern that the issue will be addressed by ensuring that IRGs give appropriate attention to the reasonableness of costs.

To reinforce the IRGs' role in assessing the appropriateness and reasonableness of proposed direct costs, NIH will undertake a concerted effort to heighten the sensitivities of IRG members to cost issues. This will include strengthening the review guidelines provided to initial reviewers and reemphasizing at future IRG meetings the need to examine proposed budgets more closely.

If NIH financial management objectives cannot be met by accepting IRG-recommended budgets, Councils and Boards, working with staff, will develop those cost control practices necessary to manage their research portfolios in accord with the principles stated above. These practices will be used in determining the appropriate level of support for each grant at the time each competing award is made. NIH shares Congressional concern over arbitrary, across-the-board budgetary reductions. To hold cost increases in line with the BRDPI, Institute and Center staff will need to adjust the initially recommended amounts so that, on the average, the cohort of competing grants in any one fiscal year will not increase by more than the BRDPI over the cohort of competing grants in the previous year.

Adherence to the BRDPI constraint can be partially accomplished by a more rigorous cost analysis of the IRG recommended budget figures. Such an analysis, which has been undertaken on a limited basis, involves obtaining and verifying cost data and evaluating specific elements of cost to determine if the proposed costs are accurate, reasonable, and allowable. This type of evaluation, which provides a higher degree of specificity and accuracy in determining costs, is carried out in close consultation with the scientific program staff and enhances current grants management practices.

In addition to cost analysis of proposed budgets, different grants as well as separate categories of grants may be adjusted by different amounts based on program considerations and scientific relevance. For example, in assessing selected proposed projects, Councils and Boards may determine that the cost of addressing a particular scientific question in the way proposed is too great relative to its program relevance and thus may recommend a reduced-scale effort or a lower-cost strategy.

NIH believes that, in implementing its financial management plan, it is critical that the quality of research not be sacrificed in the interest of awarding low-cost grants. However, as Councils and Boards review those applications within close range of the payline, they will assess not only the expected benefits of a research project but also the total costs of the proposed award. All summary statements will provide an estimate of the total costs of each proposed project, based on the IRG-recommended budget and the projected indirect costs of the applicant institution. Within this margin of excellence, where the perceived quality of the applications is statistically indistinguishable, Councils and Boards may make recommendations to fund grant applications "out of order" of the percentile ranking. In those instances in which a grant application close to the payline is not funded due to its total costs, NIH will inform the investigator of the reason for non-funding. The full effect of instituting this practice is another aspect of this financial management plan that deserves close evaluation during the coming years.

The future year commitments of the cohort of competing grants awarded in any one fiscal year will be indexed to the first year's adjusted level plus an appropriate amount for escalation. To date, this amount has been 4%, based on experience and analysis of the growth of non-competing budgets from one year to the next. In applying this escalation factor, NIH will hold the overall increase of a cohort of non-competing grants to 4%, excluding one-time, non-recurring costs. These future year amounts would be displayed on the Notice of Grant Award and no further reductions would be made except in unusual circumstances. This approach would provide stability and predictability to the commitment base for the successive years of the grant.

In summary, on an Institute-by-Institute basis, the cohort of competing grants awarded in one year will not increase by more than the BRDPI over the cohort of competing grants from the previous fiscal year; and future year commitments for any given cohort will increase by an average of 4%. It is important, however, to note that the aggregate costs of all non-competing grants in any one fiscal year (resulting from competing grants awarded in different years) will actually increase by more than 4% over the previous year. This is the result of the expiration of older, less costly grants and the influx of new, more expensive grants and changes in the mix of different types of grants.

Appendix C contains four projections developed by NIH that forecast the likely impact on the NIH budget of implementing various cost-management measures, some of which have been discussed above. These projections, based on certain assumptions, suggest the level of funding that would be necessary to sustain growth at various levels.

In keeping with the suggestion in the House Appropriations Report, opportunities for addressing public health emergencies or unique programmatic initiatives will be identified separately, above the funding base addressed in this financial management plan. It is also important to recognize that the goal of achieving a specified target number of grant awards should not overshadow NIH's need to maintain a research portfolio that reflects a judicious balance among its various funding mechanisms.

To further ensure that the average costs of grants remain stable and predictable, NIH will establish the indirect cost rate negotiated for the initial (competing) year as the rate for all years of the recommended period of support (normally one to five years). This will be a small but important contribution to making future funding levels as nearly predictable as possible.

As a longer-term issue, indirect costs must be approached as a component of better fiscal management of NIH - and taxpayer - resources. A reasonable approach to this is to re-examine the current system for grantee institutions' recovery of indirect costs. A central issue that merits scrutiny are the policies governing the separation of direct costs from indirect costs, policies that keep the latter outside the purview of the federal funding agencies. Furthermore, emphasis should be placed on creating incentives for grantee institutions to contain costs. Instead of being compelled to recover every possible allowable cost, institutions should be motivated to develop innovative approaches to sound and judicious management of federal funds. For these reasons, NIH has established a plan to conduct a careful, systematic review of the issues relative to indirect costs. The objectives of such a plan would be to review the components of indirect costs, to determine if such costs can be reasonably contained without jeopardizing the ability of grantee institutions to conduct research, and to make specific recommendations for realigning the federal system for reimbursement of indirect costs. NIH is willing to assume a major leadership role in addressing this complex issue and it will do so with the participation of the extramural community.

As competition for research support becomes keener, co-funding from other sources (i.e., funding from more than one source for separate, non-overlapping aspects of the same project) will become increasingly common, whether those sources be institutional, industrial or other government agencies. NIH will facilitate such co-funding by making appropriate modifications to its administrative policies. The availability of other sources of support will, of course, vary depending on the area of research.

Beyond implementation of the cost management measures described thus far, there is also need to undertake a second phase of financial management that will address longer-term issues such as long-range planning, indirect costs (see above), strategies to deal with unexpected public health crises, additional mathematical modeling of grant award fluctuations, alternative approaches to research training, and support of infrastructure.

C. Success Rate

The House and Senate Appropriations Reports both encouraged NIH "to modify the peer review system....eliminate the situation where 95% of applications are approved of which only half are really considered as deserving of support." To remove the semantic confusion, NIH proposes to abolish the practice of "approving" grant applications. This action would eliminate the category of approved but unfunded applications, i.e., those that contribute to the high "approval" rate.

NIH proposes that IRGs as well as Councils/Boards "not recommend for further consideration" any application that does not merit funding under any circumstances. All other applications would receive a score as well as a percentile ranking. When Councils and Boards meet, they would not review the bottom tier (e.g., the last third) of these applications. However, any Council or Board may, at its discretion, recommend singling out specific applications to be funded from the last tier on an exceptional basis as a result of scientific and/or programmatic considerations.

On applications involving biohazardous materials, unethical procedures, etc., a bar-to-award will continue to be placed, ensuring that no grants will be awarded for those projects unless such concerns are resolved.

As part of this approach, NIH will adopt the "success" rate, i.e., the rate derived by dividing the number of awards by the total number of applications reviewed, to report funding ratios. This practice is in effect in all other federal agencies.

RESEARCH TRAINING

To ensure that research training stipends keep pace with the cost of living, NIH has requested and received approval from the Public Health Service to increase stipends for all National Research Service Award trainees and fellows consistent with Congressional appropriations for FY 1991 and with programmatic needs outlined in the NIH prepared Review of the National Institutes of Health Biomedical Research Training Programs of October 1989. This request has provided stipend increases of 2.4% to 9.4%, depending on the years of previous experience and the reported disparities with corresponding housestaff salaries.

The National Academy of Sciences (NAS) has estimated that the real growth in the research training program should be approximately 3.5% per year over the period from 1989 to 1993. The NAS report recommends an overall growth of 3.84% for 1989, 3.68% for 1990, and 3.55% for 1991. Using the combined NIH and ADAMHA 12,370 Full-Time Training Positions (FTTPs) in 1987 as a base for calculation, the NAS recommends 13,794 FTTPs for NIH and ADAMHA in 1991. It is estimated that NIH and ADAMHA will actually be able to support 13,721 FTTPs, which is approximately .5% less than the NAS recommended figure.

CENTER GRANTS

The House Appropriations Report called upon NIH to fund approximately 640 center grants. Although there was no comparable provision in the corresponding Senate report, several NIH Institutes and Centers were instructed through the report language accompanying their FY 1991 appropriations to provide support for additional centers. These additional centers bring the overall number of center grants to a level that exceeds the ceiling provided by the House report. NIH recognizes the need to manage the costs of centers. However, cost control can be achieved by the total amount of funds made available for centers rather than by establishing a ceiling on the number of centers. Setting an arbitrary cap on the number of centers that can be funded jeopardizes the flexibility of NIH to take advantage of the different research and resource center environments and their multidisciplinary teams to attack problems requiring a more nearly comprehensive and longer-term approach.

It should be noted that some of the increase in number of centers is directly attributable to specific Congressional directives to establish new centers. In fact, the FY 1991 Appropriations Reports call upon NIH to create additional centers. If a ceiling were set on the total number of centers, NIH would either be forced to discontinue funding of some centers before the end of their current period of committed support or be unable to carry out these directives until some of the current center grants expire. While NIH will make every effort to contain the costs associated with center grants, it is important that NIH be provided with the flexibility to respond to new Congressional directives.

FUNDING FOR OTHER MECHANISMS, THE OFFICE OF THE DIRECTOR, AND FOR MAINTENANCE AND REPAIR OF NIH FACILITIES

NIH agrees that the funding for "Other Mechanisms" of support should be increased each year commensurate with inflation, to the extent that overall budget constraints allow. These mechanisms are integral components of a well-balanced research portfolio, and NIH is pleased that Congress has noted their importance. It is essential, however, that NIH have the flexibility to make scientific judgments regarding the relative priority of each mechanism and to allocate funds to those mechanisms that can best capitalize on the emerging scientific opportunities.

NIH is very pleased that Congress has created a contingency reserve in FY 1991 for the Director of NIH. However, the suggestion that in future years this reserve be divided equally between the Office of the Director and the individual Institutes and Centers would severely limit the Director's ability "...to correct imbalances and to be more responsive to new issues, scientific emergencies and research opportunities of high priority...." For this reason, NIH proposes that this contingency fund remain in the Office of the Director.

FY 1991 appropriations for NIH also include funds for rehabilitation of NIH's existing plant. To provide for an effective and orderly process, NIH is developing a comprehensive Facilities Revitalization Program, which identifies facility needs within a structured program that will minimize disruption to ongoing operations. This strategy will integrate new construction, renovation and maintenance requirements into a single, coordinated program so that ongoing research and clinical care, as well as anticipated growth, can be supported in accordance with modern standards. A key element of this program is the Master Plan that will provide the framework for facility management at the NIH Bethesda and Poolesville campuses and coordination with other components of the Revitalization Program.

EVALUATION OF FINANCIAL MANAGEMENT PLAN

NIH proposes that, concurrently with the implementation of this financial management plan, an internal evaluation study be instituted to determine the impact of the actions that have been outlined in this report. Since it is clear that there will be changes not only in the way in which NIH conducts business but also in the manner in which the scientific community will interact with NIH, it would be prudent to plan an evaluation to assess the effects of the policy and procedural changes that will take place in the next few years. Such an evaluation will also provide information to assist NIH in determining whether any unexpected or unanticipated issues might arise and in which ways this plan might evolve in order to maintain the preeminence of the national biomedical research enterprise and take advantage of emerging scientific opportunities while applying prudent management principles.

ISSUES FOR FUTURE CONSIDERATION

The financial management plan described in this document constitutes a first step in an overall strategy to manage the costs of research while addressing the opportunities and needs in biomedicine. Although certain actions have been proposed that will address the most immediate concerns, NIH will be re-examining continually many of the recommendations suggested here and considering other options that may be feasible. This plan sets forth the principal parameters that will guide the management of costs; however, the values for these parameters are not inalterable and may, as a result of experience and further analysis, be subject to change. While the values for any given fiscal year will be fixed for that year, NIH foresees that over time modifications may become necessary. However, such future modifications will be the result of managed change rather than uncoordinated actions.

Much of the debate on biomedical research costs has centered on research project grants. This category of awards has been an important focus of attention for Congress, the Administration, and others interested in the health of the nation's biomedical research enterprise. A great deal of attention has been drawn to the keen competition that an investigator faces in competing for a regular NIH research grant (new or renewal). However, these discussions of competing grants tend to focus attention on a relatively small component (17%) of the research project grant category and an even smaller portion (13.2%) of the total research and development budget. Within the research project grant category and especially within the overall R&D budget, there are a number of different funding mechanisms with quite different purposes and associated costs. This mix of funding mechanisms makes comparisons among the various NIH Institutes and Centers extremely difficult. Because each NIH funding component needs to address the special needs and opportunities associated with its specific mission, its research portfolio management philosophy and practices will be different from that of another component. Trans-NIH policy decisions affecting the number of competing research project grants from year to year therefore have differential effects on the options for these Institute/Center-specific management decisions.

NIH recognizes, therefore, that there is a need to develop alternative measures for assessing the overall strength of federally funded biomedical research programs and for presenting budget requests to Congress. While the total number of research projects grants (and, within that, the number of competing awards) is one metric for sizing the biomedical research enterprise, it may not be the only or even the most appropriate one. For example, it has been suggested that NIH should use the total number of full-time equivalent doctorate level scientists receiving NIH support, regardless of funding mechanism, as an alternate measure of biomedical research activity. NIH will consider this as well as other suggestions as it proceeds with implementation of the financial management plan.

In refining its financial management plan during the next several years, NIH will also be mindful of the fact that many universities and other institutions seem unduly dependent upon NIH funds. For these institutions, even small changes in appropriation patterns or funding practices can destabilize the local research environment. Such destabilization obviously runs counter to the goal of having a strong, sustained, broad-based enterprise. The issue arises in setting priorities within the FY 1992 budget request for NIH. To ensure special emphasis on research project grants and other research-intensive mechanisms within the generous increase proposed by the President, NIH assigned lowest priority to the Biomedical Research Support Grants and the shared instrument grants. This is not to say that these funds are unimportant or are used unwisely; on the contrary, local stability demands such complementary resources to the large funding instruments. But, to the extent that NIH tries to provide all types of funding, it risks diluting its efforts. Perhaps NIH should concentrate its extramural awards exclusively in those mechanisms that are available from virtually no other sources (e.g., research project grants, center grants, training grants and contracts) and encourage institutions to rely on non-NIH revenue streams and resources to finance smaller-scale but important activities such as pilot projects, bridging support, and acquisition of shared instruments. Stability of funding at the institutional level will demand multiple sources of support even if NIH continues to thrive.

SUMMARY

Starting in FY 1991, NIH will begin to move the average length of research project grants to approximately four years. Cost management measures will be taken to ensure that the average cost of research project grants increases in consonance with the Biomedical Research and Development Price Index. NIH will establish the indirect cost rate negotiated for the initial (competing) year as the rate for all years of the recommended period of support. The concept of "approving" grant applications will be abolished, and the widely used success rate will be adopted to show the ratio of applications funded to applications reviewed. Research training will be supported at the levels recommended by the National Academy of Sciences to the extent possible without jeopardizing NIH's ability to provide increases in trainee stipends. The growth of research and resource centers will be managed by the amount of NIH appropriation available for centers rather than by establishing a ceiling on the number of centers. Last, funding for "Other Mechanisms" will be increased commensurate with inflation if overall budget constraints allow.

Throughout, NIH will ensure that its primary focus remains unchanged, namely, the support of high quality research of relevance to improving human health.

APPENDIX A

TEXT FROM THE REPORT OF THE HOUSE COMMITTEE ON 1991 APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH & HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES

NATIONAL INSTITUTES OF HEALTH

The bill includes $8,317,654,000 for the 20 appropriations which together fund the programs of the National Institutes of Health (NIH). These include appropriations for the 13 research institutes, the National Center for Research Resources, the National Center for Nursing Research, the National Center for Human Genome Research, the John E. Fogarty International Center, the National Library of Medicine, the Office of the Director, and Buildings and Facilities.

The total in the bill is $694,479,000 above the President's budget request for 1991, and $1,040,871,000 above the comparable appropriations for fiscal year 1990. These figures do not include funds for research training and medical library assistance which have been deferred pending reauthorization.

The amount added by the Committee restores the number of new grants to approximately 6000, provides for a larger increase in the size of grants than proposed by the President, and addresses other specific program needs identified during Subcommittee hearings. The Committee has relied heavily on the testimony of the Acting Director of NIH regarding the distribution of additional funds among the institutes and among mechanisms.

The specific amounts with appropriate comparisons are shown in the following table:

	1990 comparable	1991 request	1991 bill	Bill increase over 1990
National Cancer Institute	$1,598,501,000	$1,658,266,000	$1,749,392,000	+$150,891,000
National Heart, Lung, and Blood Institute	1,027,861,000	1,068,026,000	1,135,589,000	+107,728,000
National Institute of Dental Research	129,851,000	134,627,000	149,592,000	+19,741,000
National Institute of Diabetes, Digestive, and Kidney Disease	557,594,000	581,477,000	613,686,000	+56,092,000
National Institute of Neurological Disorders and Stroke	477,380,000	499,196,000	545,225,000	+67,845,000
National Institute of Allergy and Infectious Diseases	815,412,000	869,382,000	944,965,000	+129,553,000
National Institute of General Medical Sciences	629,239,000	659,844,000	693,499,000	+64,260,000
National Institute of Child Health and Human Development	426,350,000	444,911,000	488,282,000	+61,932,000
National Eye Institute	229,419,000	240,287,000	254,887,000	+25,468,000
National Institute of Environmental Health Sciences	218,647,000	225,206,000	244,832,000	+26,185,000
National Institute on Aging	229,932,000	239,418,000	278,311,000	+48,379,000
National Institute of Arthritis and Musculoskeletal and Skin Diseases	162,185,000	169,338,000	191,397,000	+29,212,000
National Institute on Deafness and Other Communications Disorders	114,459,000	119,724,000	125,623,000	+11,164,000
National Center for Research Resources	334,612,000	316,658,000	353,469,000	+18,857,000
National Center for Nursing Research	29,293,000	30,894,000	37,289,000	+7,996,000
National Center for Human Genome Research	56,558,000	102,963,000	66,131,000	+9,573,000
John E. Fogarty International Center	15,656,000	16,355,000	18,682,000	+3,026,000
National Library of Medicine	72,876,000	76,725,000	80,725,000	+7,849,000
Office of the Director	89,916,000	82,975,000	106,175,000	+16,259,000
Buildings and facilities	61,042,000	86,903,000	239,903,000	+178,861,000
Total, current action	7,276,783,000	7,623,175,000	8,317,654,000	+1,040,871,000
Unauthorized programs	299,569,000	304,814,000	Defer	Defer

FINANCIAL MANAGEMENT AND LONG RANGE PLANNING

During its review of the 1991 budget for the National Institutes of Health, the Committee has heard from scientists throughout the United States that, despite large increases in funding for the NIH during the last decade, the system of Federal support for the health sciences is in crisis. While the Committee believes that this crisis has been overstated, it recognizes that problems with low numbers of new grants, high levels of downward negotiation of grant awards, and the general lack of stability in government support for the biomedical sciences are critical problems which must be addressed if the vitality and the morale of the research community are to be restored. While there are many causes of the current problem, including less funding in recent years than the Committee would have liked, it is clear that financial support for NIH as a whole is not the only issue. This can be seen from the following table showing the funding history of NIH over the last 8 years:

[Dollars in millions]

	Appropriation	Change over prior year (percent)	New grants	Total grants
Fiscal year:				
1983	$4,023	+10.5	5,389	16,921
1984	4,494	+11.7	5,493	17,305
1985	5,149	+14.6	6,246	18,537
1986	5,498	+6.8	6,211	18,796
1987	6,183	+12.4	6,453	19,583
1988	6,667	+7.8	6,213	20,202
1989	7,145	+7.2	5,382	20,681
1990	7,576	+6.0	4,577	20,260

The Committee believes that two specific problems appear to have contributed most directly to the current situation. First is the decision made by the NIH leadership to increase the average length of grants from 3.3 to 4.3 years. The Committee believes that this modification was made without sufficient attention to its impact on the number of new grants which could be awarded in future years. The Committee notes that this decision was made without consultation with the Congress. The second problem is the increasing cost of grants which has routinely exceeded all reasonable measures of inflation. NIH's inability or unwillingness to come to grips with this problem has resulted in an increase of 94% in the average cost of a grant between 1981 and 1990. This is almost double the general rate of inflation. Essentially, NIH has approved grant funding requests without regard to the amount of funds which are available in a particular year. Grant awards have then been arbitrarily reduced to stay within budget through so-called "downward negotiations". The Committee does not believe that this approach, which might have worked during earlier times when NIH was smaller and the competition for funding was less intense, is adequate for the 1990's. The current system does not serve adequately either scientists or taxpayers.

The Committee bill increases funding for the National Institutes of Health by more than $1 billion over the 1990 level. This increase will address current imbalances and support increased opportunities for improving human health through research. The Committee believes that this increased investment is fully justified by both the humanitarian and commercial potential of the biomedical sciences. In making this commitment of scarce resources, however, the Committee expects NIH to implement more aggressive cost management and cost control measures. In this context, the Committee has made its FY 1991 funding recommendations as the first step of a four year plan which NIH is expected to implement as it manages its 1991 appropriations. The Committee, in developing this financial management framework, would have preferred to be responding to a plan formulated by the NIH leadership. In the absence of such a proposal, however, the Committee believes that the following elements should form a basis for bringing more stability and predictability to NIH's current fiscal situation:

—NIH should move over the next four years to a stable research grant pool of approximately 6,000 new and 24,000 total grants. This compares to approximately 4,600 new and 20,300 total grants in 1990. The 1991 bill includes sufficient funds to support approximately 6,000 new grants.

—NIH is directed to provide necessary cost control on the research grant system by ensuring that the average length of a grant not exceed approximately 4.0 years and that the average cost of a grant not increase faster than the biomedical research deflator index. This can be accomplished by specific cost management strategies or by factoring cost into the grant selection process or both.

—The total cost of a grant, including indirect costs, should be considered at all stages of the grant review process.

—The practice of downward negotiation should be eliminated. Grants should be approved at the most economical level compatible with the science being proposed and then the average cost should be controlled through which grants are actually chosen for funding. The institutes, through their study sections and advisory councils, should aggressively eliminate any costs which they believe are unnecessary. Once this is done, a grant should be funded at the full level without arbitrary reductions. This system would apply to both project grants and centers beginning with new grant awards in 1991.

—NIH is encouraged to modify the peer review system to require that "approval" reflect a decision by a study section about whether a project merits funding based on its inherent value to biomedical research as well as meeting technical standards. This would eliminate the situation where 95% of applications are approved of which only half are really considered as deserving of support.

—Research training should be funded at the numbers recommended by the National Academy of Sciences with programmed cost of living adjustments for trainees.

—The number of center grants should not exceed approximately 640 (15 more than the 1990 level) with new center grants to be funded in future years by turnover within this base number. The Director should control an allocation system for centers with as many as 10–15 center slots reallocated each year. The overall budget for centers should be increased each year to reflect inflation. If center costs increase faster than inflation, the number of center grants should be reduced in order to adequately fund those which remain.

—Funding for other mechanisms should be increased to reflect inflation.

—The Director of NIH should have a reasonable contingency reserve to respond to emergencies or unanticipated opportunities. In 1991 this is allocated entirely to the new Director. In future years this should be divided equally between the Office of the Director and the individual institutes.

—The budget should provide adequately for maintenance and repair of NIH facilities.

The Committee recognizes that NIH may wish to modify this plan based on its experience and its judgment of the best way to accomplish common goals. In this context, the new Director of NIH is invited to submit revisions to this plan as part of the 1992 budget, or earlier if he deems it necessary. The Committee will only consider modifications, however, which are compatible with the goal of stability and predictability during a period of planned growth.

Finally, the Committee recognizes that there may be unique problems or initiatives which will need to be considered outside of the funding framework established by this plan. AIDS is an example of a public health emergency which clearly required a commitment of resources which could not be handled under normal patterns of growth. The Committee believes, however, that these situations are unusual and that this plan would provide sufficient levels of resources to deal with all but the most extreme problems. These exceptions will need to be clearly presented to the Committee and justified before they would be approved.

TEXT FROM THE REPORT OF THE
SENATE COMMITTEE ON 1991
APPROPRIATIONS FOR THE DEPARTMENTS
OF LABOR, HEALTH & HUMAN SERVICES, AND
EDUCATION, AND RELATED AGENCIES

NATIONAL INSTITUTES OF HEALTH

The bill includes $8,347,085,000 for the 20 appropriations which together fund the programs of the National Institutes of Health [NIH]. These include appropriations for the 13 research institutes as well as the National Center for Research Resources, the National Center for Nursing Research, the National Center for Human Genome Research, the John E. Fogarty International Center, the National Library of Medicine, the Office of the Director, and buildings and facilities. The total in the bill is $419,096,000 above the President's budget request for fiscal year 1991 and $770,733,000 above the comparable appropriations for fiscal year 1990. These figures include funds for research training and medical library assistance. The amount added by the Committee restores the number of new grants to approximately 6,000. The specific amounts for each of the NIH appropriations with appropriate comparisons, as well as the amounts provided for AIDS within each of the NIH appropriations are displayed at the end of this report.

Financial management

The Committee concurs with the House that the NIH needs to implement improved financial management and long-range planning.

Last year the Committee heard repeated testimony and received and reviewed a great deal of correspondence indicating that the system of Federal support for biomedical research has reached a crisis. While the Committee believes that the extent of this crisis has been overstated, it does recognize problems associated with reducing the number of new grants being approved each year, particularly the impact this has on new and first-time investigators, and high-level of downward negotiations of grant awards. These problems have developed in spite of the facts that since 1983 the Congress has doubled the size of the NIH and increased amounts requested by the administration. These increases have ranged from 14.6 percent to 6 percent each year over the preceding year.

The Committee believes that the problem of the declining number of new grants and high levels of downward negotiations of grant awards is the result largely of two situations. First is the decision made by the NIH leadership to increase the average length of grants from 3.3 years to 4.3 years, a trend which began in 1972. This situation results in ever increasing amounts of funding required for grant continuations and with any given amount of funding making less available for new grants. The second problem is that the average cost of grants has routinely exceeded all reasonable measures of inflation with the average size of a grant increasing 94 percent between 1981 and 1990. An additional trend which causes false expectations in the research community is the upward creep in the NIH approval rate of grant applications. Since 1972 the percentage of grants approved has increased from 69 percent to the 1991 estimate of 95.3 percent. Clearly this trend increases expectations for funding and also results in an ever declining award rate of grants.

The Committee concurs with the House and believes that the NIH leadership should formulate a fiscal management and long-range plan to bring more stability and predictability to the NIH current funding situation. The Committee believes that this plan should include the following elements:

—NIH should implement a cost-control system to ensure that the average length of grants does not exceed approximately 4 years and that the average cost of a grant not increase faster that the biomedical research inflation index. This should be accomplished by specific cost management strategies and by factoring cost considerations into the grant selection process.

—The total cost of a grant should be considered at all stages of the grant review process.

—NIH should modify the peer review system to require that approval reflect a decision by a study section about whether a project merits funding based on its inherent value. This will eliminate the situation where 95 percent of applications are approved but only one-half, or less, are really considered as deserving of funding.

—Research training should be funded at the numbers recommended by the National Academy of Sciences with programmed cost-of-living adjustments for trainees.

—The budget each year should adequately provide for maintenance and repair of NIH facilities.

The Committee requests that the administration submit a plan to the House and Senate Committees on Appropriations to accomplish these necessary financial management and long-range goals. The Committee would only be supportive of modifications which are compatible with the overall goal of stability and predictability. The Committee encourages the NIH to consult with the research community during the development of the long-range plan.

APPENDIX B

PERCENT REDUCTION BY IRG/COUNCIL AND I/C/D's IN NIH COMPETING RESEARCH PROJECT AWARDS

	PERCENTAGE REDUCED BY IRG/COUNCIL FROM REQUESTED AMOUNT					PERCENTAGE REDUCED BY ICD FROM COUNCIL RECOMMENDED AMOUNT					TOTAL REDUCTIONS FROM REQUESTED AMOUNT
		QUARTILE OF AWARDS BASED UPON PRIORITY SCORE					QUARTILE OF AWARDS BASED UPON PRIORITY SCORES				
	TOTAL	FIRST	SECOND	THIRD	FOURTH	TOTAL	FIRST	SECOND	THIRD	FOURTH	
1980	21.9	14.4	20.5	23.8	28.5	3.1	3.7	1.8	2.3	4.7	24.3
1981	19.7	13.2	18.4	20.8	25.9	4.6	3.7	4.0	3.9	7.0	23.4
1982	18.5	14.6	16.5	21.0	22.0	9.9	8.2	9.5	8.2	13.6	26.6
1983	18.3	14.2	17.4	19.5	22.6	9.4	9.2	8.3	9.8	10.4	26.0
1984	17.1	15.3	16.3	17.3	19.7	3.4	3.3	2.8	3.8	3.7	19.9
1985	14.7	10.9	16.1	16.6	15.6	3.8	3.5	3.0	3.4	5.6	18.0
1986	14.1	9.6	14.6	15.5	17.3	11.0	9.8	10.2	11.4	12.9	23.5
1987	13.3	9.6	12.9	14.3	16.9	7.7	7.8	7.2	8.4	7.3	20.0
1988	12.5	9.3	11.6	13.7	15.9	12.5	12.4	12.8	12.4	12.5	23.5
1989	10.9	8.4	10.9	12.4	12.1	12.9	12.1	13.5	12.3	14.1	22.4
1990	11.9	8.2	11.5	12.8	16.2	15.1	13.4	15.2	16.6	15.4	25.2

APPENDIX C

Financial Management Plan

Research Project Grants

(Dollars in thousands)

Projection A

Assumptions:
-- 4 year average length
-- 6000 competing RPGS starting in FY 1993
-- Average cost of competing adjusted by the BRDPI
-- Noncompeting based on first year's adjusted costs + 4% escalation

	1991	1992	1993	1994	1995
Noncompeting					
Dollars	$3,296,869	$3,617,637	$3,858,120	$4,162,777	$4,559,913
Numbers	15,401	16,033	16,212	16,596	17,261
Admin. Suppl.					
Dollars	20,642	21,629	22,812	24,044	25,323
Competing					
Dollars	1,180,122	1,253,537	1,371,242	1,445,289	1,522,178
Numbers	5,785	5,785	6,000	6,000	6,000
Total					
Dollars	4,497,633	4,892,803	5,252,174	5,632,110	6,107,414
Numbers	21,186	21,818	22,212	22,596	23,261
Percent Incr. over previous yr.	7.6	8.8	7.3	7.2	8.4

BRDPI for years shown is 5.99, 5.76, 5.47, 5.40, and 5.32 respectively.

Financial Management Plan

Research Project Grants

(Dollars in thousands)

Projection B

Assumptions:
-- 4 year average length
-- 5785 competing RPGS each year
-- Average cost of competing adjusted by the BRDPI
-- Noncompeting based on first year's adjusted costs + 4% escalation

	1991	1992	1993	1994	1995
Noncompeting					
Dollars	$3,296,869	$3,617,637	$3,858,120	$4,113,364	$4,458,206
Numbers	15,401	16,033	16,212	16,399	16,876
Admin. Suppl.					
Dollars	20,642	21,629	22,812	24,044	25,323
Competing					
Dollars	1,180,122	1,253,537	1,322,105	1,393,499	1,467,633
Numbers	5,785	5,785	5,785	5,785	5,785
Total					
Dollars	4,497,633	4,892,803	5,203,038	5,530,907	5,951,162
Numbers	21,186	21,818	21,997	22,184	22,661
Percent Incr. over previous yr.	7.6	8.8	6.3	6.3	7.6

BRDPI for years shown is 5.99, 5.76, 5.47, 5.40, and 5.32 respectively.

Financial Management Plan
Research Project Grants

(Dollars in thousands)

Projection C
Assumptions:
-- 4 year average length
-- 6000 competing RPGS starting in FY 1993
-- Competing grants based on initial review group recommended amount
-- Noncompeting based on initial review group recommended amount + 4% escalation

	1991	1992	1993	1994	1995
Noncompeting					
Dollars	$3,296,869	$3,617,637	$4,236,724	$4,636,202	$5,017,855
Numbers	15,401	16,033	16,212	16,596	17,261
Admin. Suppl.					
Dollars	20,642	21,629	22,812	24,044	25,323
Competing					
Dollars	1,180,122	1,253,537	1,660,033	1,749,675	1,842,758
Numbers	5,785	5,785	6,000	6,000	6,000
Total					
Dollars	4,497,633	4,892,803	5,919,569	6,409,921	6,885,936
Numbers	21,186	21,818	22,212	22,596	23,261
Percent Incr. over previous yr.	7.6	8.8	21.0	8.3	7.4

Financial Management Plan
Research Project Grants

(Dollars in thousands)

Projection D

Assumptions:
- -- 4 year average length
- -- Number of RPGS based on domestic growth ceiling permitted by the 1991 Budget Reconciliation Act
- -- Average cost of competing adjusted by the BRDPI
- -- Noncompeting based on first year's adjusted costs + 4% escalation

	1991	1992	1993	1994	1995
Noncompeting					
Dollars	$3,296,869	$3,617,637	$3,858,120	$3,983,933	$3,993,518
Numbers	15,401	16,033	16,212	15,883	15,117
Admin. Suppl.					
Dollars	20,642	21,629	22,812	24,044	25,323
Competing					
Dollars	1,180,122	1,253,537	1,192,905	1,060,786	1,120,885
Numbers	5,785	5,785	5,220	4,404	4,418
Total					
Dollars	4,497,633	4,892,803	5,073,837	5,068,763	5,139,726
Numbers	21,186	21,818	21,432	20,287	19,535
Percent Incr. over previous yr.	7.6	8.8	3.7	-0.1	1.4

BRDPI for years shown is 5.99, 5.76, 5.47, 5.40, and 5.32 respectively.

For further information, contact:

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